REMARKS

Claims 21, 22, and newly added claims 30-43 are currently pending.

Claim 21 has been amended to correct antecedent basis. No new matter has been added by this amendment.

Please add new claims 30-43. Support is found throughout the application for these new claims.

Dependent claims 30, 33, 37, and 41 are drawn to the embodiment wherein the gene product is a peptide. Specific support for this embodiment is found throughout the application and particularly at p. 22, lines 5-14, and p. 27, lines 15-22.

Dependent claims 31, 34, 38, and 42 are drawn to the embodiment wherein the gene product is a transcript. Specific support for this embodiment is found throughout the application and particularly at p. 22, lines 8-14, and p. 34, lines 5-8.

Claims 32-43 are drawn to a SAGE tag with a defined location within the transcript from which it was generated. Specific support for this embodiment is found throughout the application and particularly at p. 9, lines 9-12, p. 16, lines 4-13, and p. 48, line 25, - p. 49, line 24.

In claims 36-43, Applicants have further defined the invention as detecting a lung cancer cell from a normal lung cell. Specific support for this embodiment is found throughout the application and particularly at p. 3, lines 3-5, p. 4, lines 1-3, p.16, lines 4-13, p. 17, lines 20-22, and p. 27, lines 15-22.

In claims 40-43, Applicants have added a control sample step to the method as claimed. Specific support for the use of a control sample is found throughout the application and particularly at p. 15 lines 20-27 and p. 34 lines 5-17.

Also, a supplemental Information Disclosure Statement is being filed concurrently with this response.

As such, no new matter has been added.

Rejection Under 37 CFR 1.821(d)

The specification has been amended to correct the objection stated by the Examiner. The sequence on page 19 of the instant specification has been changed to SEQ ID NO:41. SEQ ID NO:41 has been submitted in a supplemental sequence listing.

Rejection Under 35 U.S.C. 112, First Paragraph

Enablement

The Examiner has rejected claims 21 and 22 under 35 USC 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/ or use the invention. The Examiner has stated that the instant specification has not taught or provided adequate guidance for one to obtain full-length or larger length molecules comprising SEQ ID NO:35 and has not adequately taught one of skill in the art how to detect the presence of a lung cancer cell by detecting a peptide encoded by a larger length or full length molecule comprising SEQ ID NO:35. We traverse these arguments as follows.

The novelty of the instant invention rests in the identification of SEQ ID NO:35 as over-represented in lung cancer. This sequence can be readily used by one of ordinary skill in the art to obtain larger or full length polynucleotides comprising SEQ ID NO:35. Moreover, the instant specification as written does provide guidance to for one of ordinary skill in the art to easily identify full-length or larger length molecules comprising SEQ ID NO:35. The instant specification provides a number of detailed protocols to determine the open reading frames of genes corresponding to transcripts such as SEQ ID NO:35 (see p. 17, line 23,- p. 21, line 20, and p. 51, lines 10-16). Several of these protocols were and are commercially available as kits, e.g. 5'-RACE-PCR (BRL Life Technologies, Inc.; Clontech; see p. 18, lines 6-8) and ZAP Express cDNA (Stratagene; see p. 18, lines 25-26).

In contrast to the Examiner's assertion, the availability of these kits demonstrate that determination of full-length or larger length molecules comprising SEQ ID NO:35 molecule(s) by one of ordinary skill in the art would not require undue experimentation due to the enabling teachings provided by the instant specification. The instant invention provides the novel SEQ ID NO: 35 along with specific guidance (see above) to determine the larger or full-length molecule comprising said SEQ ID NO: 35.

The Examiner additionally asserts that the specification does not provide guidance as to the peptides encoded by a molecule comprising SEQ ID NO:35. Insofar as this rejection is understood, Applicants note that the specification teaches several methods that enable one of skill in the art to express peptides from the polynucleotides comprising SEQ ID NO:35. Such methods include synthesis using standard techniques (p. 29, lines 11-13), expression using a recombinant system (p. 29, lines 17-18), or expression using gene delivery vehicles (p. 27, line 28, p. 28, line 13).

With respect to providing adequate guidance on how to detect the presence of a lung cancer cell by detecting a gene product encoded by a larger length or full length molecule comprising SEQ ID NO: 35, the specification is enabling for practice of the claimed invention because it teaches measurable gene products that are indicative of a lung cancer cell and teaches methods by which said gene products are measured.

First, the instant specification teaches that the polynucleotide comprising SEQ ID NO:35 is over-expressed and over-represented in lung cancer cells as compared to normal lung cells (see p.16, lines 4-13, p.17, lines 20-22, p.27, lines 15-22, and p.48-49). This over-representation teaches one skilled in the art that a measurable parameter exists, namely a polynucleotide comprising SEQ ID NO: 35, with which to identify a lung cancer cell as compared to a normal lung cell. Second, the instant specification clearly teaches that the presence of a gene product from such an over-expressed polynucleotide is indicative of the presence of the neoplastic condition of the cell (see p. 17, lines 20-22, p. 22, lines 5-11, and p.27, lines 15-16). The gene product can be either a polypeptide or a polynucleotide transcript (see p. 22, lines 8-11). Third, the specification provides detailed techniques with which to detect gene product

expression in a sample. These methods are provided for peptide gene products (p.22, lines 15-22; p.33, lines 25-31) or transcript gene products (p.34, lines 5-17). As a result, one of skill in the art is provided with guidance to detect the presence of a lung cancer cell in a sample using a gene product encoded by a polynucleotide comprising SEQ ID NO: 35.

Written Description

The Examiner has rejected claims 21 and 22 under 35 USC 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed had possession of the claimed invention. The Examiner contends that knowledge of the sequence of the 10-mer fragment of SEQ ID NO: 35 does not allow the skilled artisan to envision all the contemplated larger and full length nucleic acids comprising SEQ ID NO:35. The applicants respectfully disagree. As discussed above, the instant specification teaches a number of techniques, which were state of the art at the time of filing, that enable one of skilled in the art to determine the larger or full coding sequence comprising SEQ ID NO:35. Accordingly, Applicants submit that the written description requirement has been met by the specification as provided.

Rejection Under 35 U.S.C. 112, Second Paragraph

Claims 21 and 22 have been rejected under 35 U.S.C 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, claims 21 and 22 are indefinite for the recitation of "detecting any agent:peptide complex so formed" because the claims do not previously refer to "peptide". Since the claims previously refer to a gene product, they have been amended to read "detecting any agent:gene product complex

so formed". Applicants submit that in light of the claim amendments, the rejections under 35 U.S.C 112, second paragraph, should be reconsidered and withdrawn.

No fee is deemed necessary in connection with the filing of this communication. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 07-1074.

Respectfully submitted,

3/5/03
Date

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